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AMENDMENT & RESPONSE Address to: Commissioner for Patents Washington, D.C. 20231		
	Application Number	09/398,399
	Attorney Docket Number	10981620-2
	Filing Date	September 17, 1999
	First Named Inventor	Delenstarr
	Examiner	Sisson, B.
	Group Art	1655
	Title	Techniques for Assessing Nonspecific Binding of Nucleic Acids to Surfaces

Sir:

This amendment is responsive to the Office Action dated May 24, 2001. In view of the amendments to the claims and the remarks put forth below, reconsideration and allowance are respectfully requested.

AMENDMENTS

IN THE SPECIFICATION

Page 30, line 25, please replace "Triton X-100" with
--TRITON™X-100 (polyoxyethylene(10)isooctylphenyl ether)--.

IN THE CLAIMS

Cancel Claims 10~~32~~ and 34~~49~~.

Please enter the following new claims:

--50. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with a collection of substrate bound probe nucleic acid features that includes at least one background nucleic acid feature that minimally binds to its complementary target under said hybridization conditions; and

(b) detecting the presence of target nucleic acids hybridized to said collection of probe nucleic acid features.

51. The hybridization assay according to Claim 50, wherein said sample of target nucleic acids is labeled with a detectable label prior to said contacting step.

52. The hybridization assay according to Claim 50, wherein said sample of target nucleic acids is labeled with a detectable label between said contacting and detecting steps.

53. The hybridization according to Claim 50, wherein said method further comprises a washing step between said contacting and detecting steps.

54. The method according to Claim 50, wherein said method further comprises subtracting a detected signal from said at least one background feature from signal detected from any other probe nucleic acid feature of said collection of substrate bound probe nucleic acid features.

55. The method according to Claim 50, wherein said collection of substrate bound probe nucleic acid features is an array of nucleic acid features.

56. The method according to Claim 50, wherein said hybridization assay is a method of estimating the background noise in a hybridization assay.

57. The method according to Claim 50, wherein said method is a method of validating a test background feature.

58. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with a collection of substrate bound probe nucleic acid features that includes at least one background nucleic acid feature, wherein said at least one background feature is made up of a probe nucleic acid selected from the group consisting of SEQ ID NOS: 05 to 32 or a probe that similarly minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.; and

(b) detecting the presence of target nucleic acids hybridized to said collection of probe nucleic acid features.

Sub 62 cont

59. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with a collection of substrate bound probe nucleic acid features that includes at least one background nucleic acid feature, wherein said at least one background feature is made up of a probe nucleic acid that minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.; and

(b) detecting the presence of target nucleic acids hybridized to said collection of probe nucleic acid features.

E1 cont'd

60. A hybridization assay comprising:

(a) contacting a sample of detectably labeled target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with an array of probe nucleic acid features that includes at least one background nucleic acid feature that minimally binds to its complementary target under said hybridization conditions;

(b) separating non-hybridized target nucleic acids from said array; and

(c) detecting the presence of target nucleic acids hybridized to said array probe nucleic acid features.

61. The method according to Claim 60, wherein said method further comprises subtracting a detected signal from said at least one background feature from signal detected from any other probe nucleic acid feature of said array.

Sub 63

62. A hybridization assay comprising:

(a) contacting a sample of detectably labeled target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with an array of probe nucleic acid features that includes at least one background nucleic acid feature, wherein said at least one background feature is made up of a probe nucleic acid selected from the group consisting of SEQ ID NOS: 05 to 32 or a probe that similarly minimally binds to an

R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.;

(b) separating non-hybridized target nucleic acids from said array; and

(c) detecting the presence of target nucleic acids hybridized to said array probe nucleic acid features.

63. A hybridization assay comprising:

(a) contacting a sample of detectably labeled target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with an array of probe nucleic acid features that includes at least one background nucleic acid feature, wherein said at least one background feature is made up of a probe nucleic acid that minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.;

(b) separating non-hybridized target nucleic acids from said array; and

(c) detecting the presence of target nucleic acids hybridized to said array probe nucleic acid features.

64. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with an array of probe nucleic acid features that includes at least one background nucleic acid feature that minimally binds to its complementary target under said hybridization conditions;

(b) separating non-hybridized target nucleic acids from said array;

(c) detectably labeling target nucleic acids hybridized to said array of probe nucleic acid features; and

(d) detecting the presence of target nucleic acids hybridized to said array of probe nucleic acid features.

65. The method according to Claim 64, wherein said method further comprises subtracting a detected signal from said at least one background feature from signal detected from any other probe nucleic acid feature of said array.

66. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with an array of probe nucleic acid features that includes at least one background nucleic acid feature, wherein said at least one background feature is made up of a probe nucleic acid selected from the group consisting of SEQ ID NOS: 05 to 32 or a probe that similarly minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.;

(b) separating non-hybridized target nucleic acids from said array;

(c) detectably labeling target nucleic acids hybridized to said array of probe nucleic acid features; and

(d) detecting the presence of target nucleic acids hybridized to said array of probe nucleic acid features.

67. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with an array of probe nucleic acid features that includes at least one background nucleic acid feature, wherein said at least one background feature is made up of a probe nucleic acid that minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.;

(b) separating non-hybridized target nucleic acids from said array;

(c) detectably labeling target nucleic acids hybridized to said array of probe nucleic acid features; and

(d) detecting the presence of target nucleic acids hybridized to said array of probe nucleic acid features.

68. A kit for use in a hybridization assay, said kit comprising:

a collection of substrate bound probe nucleic acid features that includes at least one background nucleic acid feature that minimally binds to its complementary target under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe.

69. The kit according to Claim 68, wherein said at least one background feature is made up of a probe nucleic acid selected from the group consisting of SEQ ID NOS: 05 to 32 or a probe that similarly minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.

70. The kit according to Claim 69, wherein said at least one background feature is made up of a probe nucleic acid that minimally binds to an R6G-labeled yeast cRNA target pool according to the test assay described in Example 3.B.

71. A hybridization assay comprising:

(a) contacting a sample of target nucleic acids under hybridization conditions that require a target nucleic acid of 14 nucleotides in length to have at least 70% sequence identity with a probe in order to hybridize to said probe with a collection of substrate bound probe nucleic acid features that includes at least one background nucleic acid feature made up of background probes that do not selectively bind to any of said target nucleic acids; and

(b) detecting the presence of target nucleic acids hybridized to said collection of probe nucleic acid features.

72. The hybridization assay according to Claim 71, wherein said sample of target nucleic acids is labeled with a detectable label prior to said contacting step.

73. The hybridization assay according to Claim 71, wherein said sample of target nucleic acids is labeled with a detectable label between said contacting and detecting steps.

74. The hybridization according to Claim 71, wherein said method further comprises a washing step between said contacting and detecting steps.

75. The method according to Claim 71, wherein said method further comprises subtracting a detected signal from said at least one background feature from signal detected from any other probe nucleic acid feature of said collection of substrate bound probe nucleic acid features.

76. The method according to Claim 71, wherein said collection of substrate bound probe nucleic acid features is an array of nucleic acid features.

77. The method according to Claim 71, wherein said hybridization assay is a method of estimating the background noise in a hybridization assay.

78. The method according to Claim 71, wherein said method is a method of validating a test background feature. --

REMARKS

Formal Matters

Claims 50 to 78 are pending after entry of the amendments set forth herein.

Claims 10-32 and 34-49 were examined and rejected.

New Claims 50 to 78 find support in the originally pending Claims 10-32 and 34-49 and throughout the specification/working exemplification. As such, no new matter is added by these claims and their entry by the Examiner is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

Claims 10-32 and 34 to 49 were rejected under 35 U.S.C. § 112, 1st ¶ for the asserted reason that the specification is non-enabling for these claims. In view of the cancellation of these claims, this rejection is moot.

With respect to new claims 50 to 78, it is respectfully submitted that these claims are fully enabled by the specification. For example, newly introduced Claim 50 is directed to a hybridization assay in which the array or analogous set of features employed is one that includes at least one background nucleic acid feature. The background nucleic acid feature

element is further described in the claim as a feature made up of nucleic acids that minimally bind to their complementary target under specified hybridization conditions recited directly in the claim. Thus, the newly presented claims require the use of a set of features, e.g., an array, that includes at least one background feature that at most minimally binds to its complementary target nucleic acid under specified stringent hybridization conditions.

In support of the pending claims, the specification provides extensive generic description of the background features. See e.g., page 16, lines 15 to 20; and page 21, line 25 to page 22, line 5. The specification also provides extensive description of specific types of background features. See e.g., page 22, line 6 to page 23, line 17. In addition, working exemplification showing actual use of a number, e.g., 28 different probes (SEQ ID NOs:05 to 32), of specific background features is provided beginning at page 29, line 20 of the specification. As such, the specification provides both an extensive generic description of what a background probe is, as well as 28 specific representative background probes and shows the use of these 28 specific representative background probes.

The specification also provides a full description of the hybridization conditions that are employed in the subject assays. For example, the hybridization conditions recited in the claims are discussed in the specification at page 17, line17 to page 28, line 16. The working exemplification also provides a report of specific hybridization conditions in which the arrays having background features were actually employed and shown to work as claimed. See e.g., page 30, lines 23 to 29. As such, the specification provides both a generic teaching of suitable hybridization conditions and specification representative hybridization conditions shown to work as claimed.

Therefore, unlike the cited *Genentech* case, in the present application there is a complete disclosure of the starting materials employed in the subject methods and of the conditions employed in the subject methods.

As such, it is respectfully submitted that Claims 50 to 70 are fully enabled by the specification.

Claims 34[2] to 39 were rejected under 35 U.S.C. § 112, 1st ¶ as assertedly containing subject matter that was not sufficiently described in the specification so as to comply with the written description requirement. Specifically, the Examiner asserts that these claims were so broad as to encompass any number of probes that can be used to bind to any nucleic acid target. In view of the cancellation of these claims, this rejection is moot.

With respect to the newly presented kit claims, it is respectfully submitted that this rejection will not be applicable to these newly presented claims for the following reasons.

The MPEP at § 2163.02 provides the standard for satisfying the written description requirement:

> The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

In the present case, the Applicant is claiming a kit in which one of the elements is a set of features, e.g., an array, where the set includes at least one background feature. The recited background feature is clearly defined in the claim as one that minimally binds to its target nucleic acid under hybridization conditions specified in the claim.

As such, the background features that may be present on the arrays of the kits are ones that must meet clearly specified criteria, and therefore belong to a defined class of nucleic acids, where this class does not include any and all nucleic acids.

As pointed out above, the specification provides a complete description of what is meant by background features. Furthermore, the specification provides 28 specific probe sequences that are shown to work as background features.

Therefore, it is respectfully submitted that the specification does convey to one of skill in the art that the Applicant is in possession of the invention as claimed and therefore that the Applicant has provided adequate written description for the pending claims.

Conclusion

The applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Gordon Stewart at 650 485 2386. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

Respectfully submitted,

Date: 9.19.01

By: _____
Bret E. Field
Registration No. 37,620